

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Sophie Lotersztajn et al.

Application No.: 10/598,736

Filed: September 8, 2006

Art Unit: Not Yet Assigned

For: USE OF ANTAGONISTS OF THE CBI
RECEPTOR FOR THE MANUFACTURE
OF A COMPOSITION USEFUL FOR THE
TREATMENT OF HEPATIC DISEASES

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:



This IDS is being filed before the First Office Action¹.

¹ The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

- ☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action².
- ☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee³.

Certifications:

If checked, the undersigned makes the following statement(s):

- ☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

² The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

³ The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application less than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

- ☒ A copy of the International Search Report dated June 29, 2005 is attached hereto. A copy of the references are not enclosed as they have been communicated to the International Bureau.
- ☒ A legible copy⁴ of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

⁴ A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

☐ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

☐ A translation of the relevant portions of the non-English language information⁵;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)⁶ of the communication from a foreign patent office in a counterpart foreign application in which the information was cited; or

☐ This information is contained in the specification of the present application.

☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. _____, filed _____, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

⁵ 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, "is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c)."

⁶ The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. MPEP §609 III A(3).

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: September 12, 2006

Respectfully submitted,

By 
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|---|---|----|---|--------------------------|--------------------|
| Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/598,736 |
| | | | | Filing Date | September 8, 2006 |
| | | | | First Named Inventor | Sophie Lotersztajn |
| | | | | Art Unit | Not Yet Assigned |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | C0300.0022 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | AA* | US-5,939,429 | 08-17-1999 | Sanyal et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | BA | -WO 2005/046689 A2 | 05-26-2005 | | | |
| | BB | -WO 2004/058744 A | 07-15-2004 | | | |
| | BC | -WO 2004/007551 A | 01-22-2004 | | | |
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| | BF | -WO 03/063781 | 08-07-2003 | | | |
| | BG | -WO 03/087037 | 10-23-2003 | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(II)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | CA | P. Grenard et al., "Reduced Liver Fibrosis in CBI Receptor Knockout Mice", Journal of Hepatology, Vol. 40, pg. 8 (April 2004) | |
| | CB | Batkai et al., "Endocannabinoids Acting at Vascular CBI Receptors Mediate the Vasodilated State in Advance Liver Cirrhosis", Nature Medicine, Nature Publishing Co., Vol. 7, No. 7, pgs. 827-832 (July 2001) | |
| | CC | Gabbay et al., Treatment with an Endocannabinoid Antagonist Improves Neurological Function and Survival in an Animal Model of Fulminant Hepatic Failure, Hepatology, Vol. 38, No. 4, pg. 541A (October 2003) | |
| | CD | Julien et al., "Activation of cannabinoid receptors leads to apoptosis of human hepatic myofibroblasts", Hepatology, Vol. 36, No. 4, pg. 260A (October 2002) | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|-----------------------|-----------------|--------------------|------------|
| Examiner Signature | /Ibrahim Boril/ | Date Considered | 06/28/2011 |
|-----------------------|-----------------|--------------------|------------|

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.B./